

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Adrenaline Bitartrate (Adrenaline Acid Tartrate) BP (Item No. 41030120)	Spec. No. : SP-AK30-A001
Reference(s) : BP 2016 p. I-78 to I-79	Rev. No. : 07
Other Requirements : -	Page : 1/2

BP 2016

Test Parameters	Specifications	
Description	White, crystalline powder, odourless.	
Solubility	Freely soluble in water, slightly soluble in ethanol (96%).	
Identification		
A. Specific optical rotation	The specific optical rotation of the residue (adrenaline base) is -53.5 to -50, determined using a 20.0 g/l solution in 0.5 M HCl.	
B. Infrared absorption spectrophotometry	Conforms to IR standard spectrum.	
C. Tartrates Test	A dark-blue colour develops. Allow to cool and pour the solution into water. The colour changes to red.	
Appearance of solution	The solution is not more opalescent than reference suspension II and not more intensely coloured than reference solution BY ₅ .	
Related substances	Impurity A	Not more than 0.3%.
	Impurity B (Noradrenaline)	Not more than 0.2%.
	Impurity C (Adrenalone)	Not more than 0.2%
	Impurity D	Not more than 0.1%.
	Impurity E	Not more than 0.1%.
	Unspecified impurity	Not more than 0.10%.
	Total impurities	Not more than 0.6%.
Loss on drying	Not more than 0.5%.	
Sulfated ash	Not more than 0.1%.	
Assay	98.5 – 101.0% of Adrenaline bitartrate (C ₁₃ H ₁₉ NO ₉), calculated with reference to the dried substance.	

Prepared by : Sunanee, 03/06/20 Head of Raw Material Standard Section 1	Reviewed by : Tarnmee, 03/06/20 Director of Raw Material Standard Division	Approved by : Vichin Ruengprongroj, 24/06/20 Director of Quality Assurance Department (Acting)	Eff. Date 30/06/20
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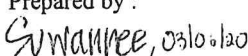
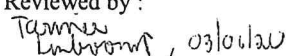
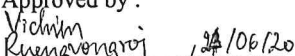
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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Adrenaline Bitartrate (Adrenaline Acid Tartrate) BP (Item No. 41030120)
Sampling plan	1. N Plan ($\sqrt{N} + 1$) : for other tests. 2. 100% Identification.
Testing procedure	Tests to be performed as per current version of WI-AK30-A001.
Storage condition	To be stored in an airtight container, or preferably in a sealed tube under vacuum or under an inert gas, protected from light.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
05	อ้างอิง spec เป็น BP 2011	31/10/11
06	Update spec. เป็น BP 2016 เนื่องจากเอกสารมีอายุมากกว่า 3 ปีจึงต้องทบทวน โดยเนื้อหาของ BP 2011 และ BP 2016 เหมือนกัน อ้างอิง CR No. AN80-59087	24/05/16
07	เอกสารมีอายุครบ 3 ปี จึงต้องทบทวน อ้างอิงตาม BP 2016 เพื่อให้สอดคล้องกับ Adrenaline injection ซึ่งขึ้นทะเบียนตาม Monograph BP 2016 (วัตถุต้น Adrenaline bitartrate BP 2016 เทียบเท่ากับ BP 2020 ส่วน Adrenaline injection BP 2020 มีหัวข้อตรงเพิ่มขึ้นจาก BP 2016)	30/06/20

Prepared by :  Head of Raw Material Standard Section 1	Reviewed by :  Director of Raw Material Standard Division	Approved by :  Director of Quality Assurance Department (Aching)	Eff. Date 30/06/20
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